

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

September 02, 2014.

EPA Reg#: 84189-1		DP Barcode: 422328	
		Submission #: 938526	
Product name: Product EP 1%		Registrant: Rudolf GMBH & CO	
Reviewer's name: Salvador Rodriguez		AD/PSB/CTT- Product Chemistry	
Agency due date: 11/18/14		PSB received date: 08/22/14	
CTT received date: 08/22/14		Science due date: 11/18/14	
Formulation type: EP			
Integrated system: <input checked="" type="checkbox"/>		Non-integrated system	Food use: <input type="checkbox"/> Non food use: <input checked="" type="checkbox"/>
Action Code:		Date Completed: September 02, 2014.	
PC Code	CAS #	Active Ingredient Names	% wt (label)
072506	7783-90-6	Silver Chloride	0.2
Test Lab: Eurofins Product Safety Labs.			
MRID(s): 49440301			
Approver: Karen P. Hicks		Approved date: September 02, 2014.	
Guideline: OPPTS Guideline Series 830.6317 "Storage Stability" & 830.6320 "Corrosion Characteristics"			
Comments:			

(09/05/14)

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MEMORANDUM

SUBJECT: Product Chemistry Review for EPA File Symbol: 84189-1
Product Name: **Product EP 1%**
DP Barcode: 422328

CODE: 320

DATE DUE: 11/18/14

FROM: Salvador Rodriguez, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Eric Miederhoff/ Zebora Johnson
PM Team 33.

A handwritten signature in black ink, appearing to be 'S. Rodriguez'.

Applicant: Rudolf GMBH & Co.

PRODUCT FORMULATION FROM LABEL:

<u>Active Ingredient(s)</u>	<u>%w/w</u>
Silver Chloride.....	0.2

BACKGROUND:

The Registrant, Rudolf GMBH, has submitted the OPPTS Guideline Series 830.6317 & 830.6320, to support the registration for the product **Product EP 1%**. The product chemistry reviewer has received the following documents:

- Transmittal letter, dated 07/31/14. MRID#: 49440300
- Confidential Statement of Formula, dated 07/19/13, for the basic formulations. (Reference).
- OPPTS Guideline Series 830.6317 & 830.6320. Study titled: "Product EP-1%: Storage Stability and Corrosion Characteristics". MRID #: 49440301
- Certification with respect to Citation of Data, pin punched on 07/31/14.
- Data matrix, pin punched on 07/31/14.

FINDINGS:

1. OPPTS 830.6317 & 830.6320 guidelines Group B product chemistry data requirements applicable to end-use products have been met. MRID # 49440301
2. The test substance was stored at room temperature in a dark colored, high density polyethylene (HDPE), in a non-climate controlled warehouse for one year. Data obtained in this study verifies that the test substance is stable for a period of at least one year.
3. The results of the long-term storage and corrosion characteristics of the test material have been determined. The study is in accordance with the requirements of the US EPA, Office of Prevention, Pesticides and Toxic Substances, Series 830: Products Properties Test Guidelines OPPTS 830.6317 & 830.6320.
4. After 12 months at room temperature, no pitting, no thinning, no warping, no change in color, no cracks holes or mottling were noted for the commercial packaging material. Upon mechanical deformation, neither the container nor the closure cracked or split. In conclusion there was no significant change in the active ingredient content of the test material during the 12 months storage.

Timepoint (Months)	Wt. % Content of Silver Chloride (Mean)
Zero Time	0.21
Three Months	0.21
Six Months	0.20
Nine Months	0.20
Twelve Months	0.20

CONCLUSIONS

Product Science Branch of Antimicrobials Division finds the proposed OPPTS Guideline Series 830.6317 & 830.6320 Group B product chemistry data requirements for the sanitizer & algacide, non- integrated, non-food-use, end-use product **EPARN: 84189-1** to be acceptable. The results of the “One Year Storage Stability and Corrosion Characteristics” studies indicates that the concentration of the active ingredient (AI), is within the EPA Standard Certified Limits.